



Food and Drug Administration
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April 16, 2015

Rex Medical, LP
% Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K143405

Trade/Device Name: Option™ Elite Vena Cava Filter 100cm System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: March 13, 2015
Received: March 17, 2015

Dear Susan Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143405

Device Name

Option(TM) ELITE Vena Cava Filter 100cm System

Indications for Use (Describe)

The Option(TM) ELITE Vena Cava Filter 100cm System is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism when anticipated benefits of conventional therapy are reduced;
- Chronic, recurrent pulmonary embolism when anticoagulation therapy has failed or is contraindicated

The filter may be retrieved according to the instructions supplied in section entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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555 North Ln, Suite 5035
Conshohocken, PA 19428

Traditional 510(k): Device Submission
Option™ ELITE Vena Cava Filter 100cm System

510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K143405

Submitter: Rex Medical, L.P.
555 North Ln, Suite 5035
Conshohocken, PA 19428

Contact Person: Erich Bressler
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Date Prepared: April 15, 2015

Trade Name: Option™ ELITE Vena Cava Filter 100cm System

Common Name: Cardiovascular Intravascular Filter
(21 CFR 870.3375, Product Code DTK)

Predicate Device(s):
K133243 Option™ ELITE Vena Cava Filter System

Device Description

The Option™ ELITE Vena Cava Filter is designed for the prevention of recurrent pulmonary embolism via percutaneous delivery in the inferior vena cava (IVC).

The Option ELITE Vena Cava Filter 100cm System is designed for IVC filter insertion, delivery, deployment and placement via the popliteal and antecubital approach.

The self-centering Option™ ELITE Filter is laser cut from nickel –titanium alloy (Nitinol) tubing. The Option™ ELITE Filter consists of shape memory Nitinol struts emanating from a central location and is designed for optimal clot capture. Retention anchors (retention hooks) are located at the caudal portion of the filter. These anchors are intended for filter fixation to the vessel wall. The Option™ ELITE Filter is intended to be used in caval diameters up to 30mm. A retrieval hook is centrally located at the cranial extremity.

The constrained Option™ ELITE Filter is flexible and expands to the internal diameter of the IVC upon deployment. The Option™ ELITE Filter imparts an outward radial force on the luminal surface of the vena cava to ensure proper positioning and stability. The Option™ ELITE Filter is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.

The introduction kit is comprised of a filter housed in a filter cartridge, Catheter Sheath Introducer (5F ID),

Angiographic Vessel Dilator with an open end, and a Pusher with deployment marker. The Angiographic Vessel Dilator has side holes and 2 radiopaque markers, separated by 32mm (between the marker bands), that provide linear measurement of the inferior vena cava and assists in angiographic visualization when radiopaque contrast is delivered. The pusher advances the filter through the Catheter Sheath Introducer up to the deployment marker, and is then used to fix the filter in place during uncovering. The location of the distal end of the Catheter Sheath Introducer can be controlled by rotating the entire device to position the Catheter Sheath Introducer in the center of the vena cava. The Filter Cartridge houses the Option™ ELITE Filter. The body of the Cartridge has text and colored arrows printed on it that identify assembly orientation; femoral is printed in green and jugular is printed in blue. The femoral orientation is used for the popliteal approach and the jugular orientation is used for the antecubital approach. The arrow of the desired access site will point into the Catheter Sheath Introducer hub. The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

Intended Use:

The Option™ ELITE Vena Cava Filter 100cm System is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism when anticipated benefits of conventional therapy are reduced;
- Chronic, recurrent pulmonary embolism when anticoagulation therapy has failed or is contraindicated

The filter may be retrieved according to the instructions supplied in section entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

This is the same intended use as previously cleared for the Option™ ELITE Vena Cava Filter System (K133243).

Technological Characteristics:

The Option™ ELITE Vena Cava Filter 100cm System is similar with regards to materials, intended use, principles of operation and technological characteristics to the predicate device. Results of bench testing demonstrate Option™ ELITE Vena Cava Filter 100cm System is as safe and effective as the legally marketed predicate device.

Modifications to Existing Technology:

The effective length of the Option™ ELITE Vena Cava Filter 100cm System has been increased from 70cm to 100cm to enable filter insertion through either the antecubital approach or popliteal vein. The vessel dilator, sheath introducer and pusher have increased functional lengths. All other kit components including the Option™ ELITE filter are identical to the predicate device. The system packaging has been modified to accommodate the longer system. Identical materials are used for the new packaging as compared to the predicate device.

Non-Clinical Performance Testing:

All testing performed on the Option™ ELITE Vena Cava Filter 100cm System was derived from the risk assessment which evaluated the safety and performance of the design modifications. Test methodology and acceptance criteria were derived from Rex Medical and from related ISO standards for evaluation of this device.

- Simulated use testing

A simulated use model that adequately represented the deployment from an antecubital/popliteal approach into a clinically challenging anatomy for this device was used for testing. Relevant deployment forces and filter tilt angles were measured. The occurrence of failures, filter or delivery system damage, excessive resistance, filter off the vessel wall, and tilting when removing the guidewire were recorded. A discussion regarding the testing for the insertion, deployment and placement of the filter using the antecubital/popliteal approach compared with the jugular/femoral approach was also provided.

- ISO Standards: ISO 10555-1, ISO 10993-1

Conclusion:

Rex Medical considers the Option™ ELITE Vena Cava Filter 100cm System to be substantially equivalent to the predicate device listed above. The conclusions are based on performance testing and similarities in indications for use, materials, technological characteristics, principle of operation and design features.